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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,423	01/10/2002	Tze-Bin Chou	529872000100	1091

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,423

Applicant(s)

CHOU, TZE-BIN

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-16,18,20,22-25 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-16,18,20,22-25,27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed June 17, 2004.

Amendments were made to the claims. Specifically, claims 3, 17, 19, 21 and 26 were cancelled.

Claims 1, 2, 4-16, 18, 20, 22-25 and 27-34 are pending in the instant application. Claims 29-34 are withdrawn as being drawn to a non-elected invention. Claims 1, 2, 4-16, 18, 20 22-25 27 and 28 are under examination in the instant application. Any rejection of record in the previous Office Action, mailed January 13, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Specification

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification is not in the proper English vernacular. **This objection is maintained from the previous Office Action.**

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by

Art Unit: 1636

being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

The minor corrections are insufficient to correct the defects in the vernacular of the instant specification. The opinion that the current amended specification is sufficient to provide a written description of the invention is not evidence that the specification is in compliance with providing a specification in the proper English vernacular. Additionally, the Office has provided numerous examples of improper grammar throughout the specification, which is sufficient evidence to require a substitute specification in the proper English vernacular. As such, a substitute specification is required in response to this Office Action.

Claim Objections

Claims 14-16, 18 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claims 14-16, 18 and 20 as amended are no longer within the scope of the claim from which they depend. Claim 1 is drawn to a method of making a *Drosophila* cFRT that is insensitive to a P transposase but remains sensitive to FLP; thus, the metes and bounds of the claimed method is for the production of a cFRT. However, claims 14-16, 18 and 20 are not drawn to methods of making such a cFRT. Rather, they are directed towards methods of using a cFRT, which is outside of the scope of

Art Unit: 1636

making a cFRT. As such, these claims are now objected to as failing to further limit the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-16, 18, 20, 22-25, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112, First Paragraph

Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive. The following grounds of traversal are presented:

1. Applicant asserts that it is clear that the claimed invention comprises "causing a local and imprecise transposition in the FRT chromosome containing a P[FRT] insertion with a selectable marker gene, followed by steps for examining sensitivity or insensitivity to P transposase and for sensitivity or insensitivity to FLP" (see for example page 17 of Applicant's response). As such,

Art Unit: 1636

Applicant contends that the skilled artisan would be reasonably capable of practicing the invention as claimed.

The argument has been considered but is not found convincing. Despite the assertion that the claim includes steps for “examining sensitivity or insensitivity to P transposase and for sensitivity or insensitivity to FLP,” these steps are not *clearly* set forth in a definite manner. Rather, the claims first set forth indefinite method steps for obtaining “screened products” without saying what characteristics a “screened product” must have in order to be considered “obtained.” These “screened products” are then put through a second indefinite process to identify “candidate products” that can be obtained by obtaining “candidate products;” however, it is unclear what characteristics a “candidate product” must have in order to be considered “obtained.” It is not clear from the claim that the method steps that are argued to be present in the claims are actually set forth therein. Absent this clarity/definiteness in the method steps, the skilled artisan cannot use the method.

It is reiterated that the enablement rejection is set forth because of the overall indefiniteness of the method steps (see for example the rejections under 35 USC § 112, second paragraph). Because the method steps in the amended claims are not definite (even though the arguments can be considered definite), the arguments cannot be considered representative of the contents of the claims. As such, the rejection as set forth previously is maintained.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1636

Claims 1, 2, 4-16, 18, 20, 22-25, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 (and their dependent claims) are indefinite for the phrase "screening...for immobility of said selection marker." This phrase is indefinite because the immobility of the selection marker is relative, and it is unclear from the claim if the immobility of the marker is in response to treatment with a P transposase, or in response to treatment with FLP. Because it is unclear what the immobility is with regard to, it is unclear how to obtain a "screened product." It would be remedial to indicate what the immobility of the marker gene is in relation to (i.e., immobility of said selection marker upon contact with a P transposase or a FLP). **This rejection is necessitated by amendment of the claims.**

Claims 1, 3 and 22 (and their dependent claims) are rejected for the term "homozygous viability." **This rejection is maintained for the reasons set forth in the previous Office Action concerning the use of the term in claims 3, 5 and 26.**

Claims 1 and 22 (and their dependent claims) are rejected for the use of the phrase "examining recombination accessibility of FRT sequences contained in a clipped P[FRT] insertion by the presence of said FLP to obtain said candidate products." The indefiniteness stems from two distinct issues. First, it is unclear if the examination constitutes determining the presence of a FLP in the insertion, if it entails the measurement of the ability of a FLP recombinase to recognize/bind/enzymatically act upon the insertion sequence, or if it requires something entirely different. Secondly, it is unclear as to how the FLP recombinase that is present in the claim language is related to obtaining "said candidate products." As such, the

Art Unit: 1636

method step for obtaining a "candidate product" is unclear and indefinite. **This rejection is necessitated by amendment of the claims.**

Claims 1 and 22 (and their dependent claims) are reject for use of the term "desired products." The term "desired products" is a relative term which renders the claim indefinite. The term "desired products" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is particularly noteworthy that the desirability of a given product may be determined by the aforementioned method steps. However, because the characteristics of the "desired products" obtained in the preceding method steps (and indeed the method steps themselves) are indefinite, it is impossible to determine when a given product can be considered "desirable." **This rejection is necessitated by amendment of the claims.**

Claims 1 and 22 (and their dependent claims) recite the limitation "said examining process" in step (d) of the claimed methods. There is insufficient antecedent basis for this limitation in the claim. **This rejection is necessitated by amendment of the claims.**

Claim 8 is rejected for the phrase "(3) a sequence that is missing of DNA sequences other than those defined in item (1) and in item (2)." **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claim 8 is rejected for the recitation of the phrase "through one sequence of." It is unclear from the use of this phrase as to whether the following sequences are where the target sequences are damaged/altered, or if these sequences are used in the process of damaging the

Art Unit: 1636

target sequence (i.e., are the sequences the object of the damage, or the perpetrator). **This rejection is necessitated by amendment of the claims.**

Claim 11 is rejected for recitation of the term "DNA configuration." It is unclear what is being measured with regard to a "DNA configuration" (e.g., it is unclear if a DNA configuration concerns the particular nucleic acid sequence, secondary structure, three dimensional structure, condensation level, or level of transcriptional activation of the cFRT, or some other parameter).

This rejection is necessitated by amendment of the claims.

Claim 12 is rejected for the recitation of the phrase "retains the functions of a wild type chromosome for genetic manipulations." It is unclear if this phrase means that the resulting chromosome maintains the ability to be further mutated/genetically manipulated, if it retains the ability to cause mutations in another molecule, or something else. **This rejection is necessitated by amendment of the claims.**

Claim 13 is rejected for use of the term "alternatively" without providing an alternative. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claim 13 is rejected because it remains unclear how a mutagen or an X-ray can cause the physical movement of a chromosome, as is set forth in the claim. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112, Second Paragraph

Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive. The following grounds of traversal are presented:

Art Unit: 1636

1. It is asserted that attempts have been made to address the rejections set forth by the Office (see for example page 18 of Applicant's response).

The arguments have been considered but are not found convincing because the rejections that are maintained persist in spite of the alleged attempts to obviate them. For example, no argument or amendment is made regarding the indefiniteness of Claim 8, part (3) as set forth in the previous Office action and reiterated above. Since these rejections have been set forth in the previous Office Action, and no specific traversal indicating the impropriety of the rejections is set forth by Applicant, the rejections are maintained as proper.

Allowable Subject Matter

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1636

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER